IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

AZIENDE CHIMICHE RIUNITE ANGELINI FRANCESCO A.C.R.A.F. S.p.A.,	)	
Plaintiff,	)	
v.	)	Civil Action No. _____
AUROBINDO PHARMA USA INC.,	)	
Defendant.	)	

COMPLAINT

Plaintiff AZIENDE CHIMICHE RIUNITE ANGELINI FRANCESCO A.C.R.A.F. S.p.A. ("Plaintiff"), alleges as follows:

1. This is an action for patent infringement under the patent laws of the United States, Title 35, United States Code, that arises out of the filing, made by Aurobindo Pharma USA Inc. ("Aurobindo"),[1] of an Abbreviated New Drug Application ("ANDA") with the U.S. Food and Drug Administration ("FDA") seeking approval to engage in the commercial use or sale of a generic version of DESYREL® (trazodone hydrochloride) in tablet form in doses of 50, 100, 150, and 300 mg, before the expiration of U.S. Patent No. 8,133,893 ("the '893 patent"). The '893 patent is listed in Approved Drug Products with Therapeutic Equivalence Evaluation (the "Orange Book").

2. DESYREL® is a selective serotonin reuptake inhibitor indicated for the treatment of major depressive disorder.

[1] The Aurobindo Notice Letter identifies the sender as "Aurobindo Pharma USA Inc."; however, the same entity appears to have been incorporated in Delaware under the name "Aurobindo Pharma U.S.A., Inc."

3. Aurobindo notified Plaintiff, by letter dated October 11, 2019 ("Aurobindo's Notice Letter") that it had submitted to the FDA ANDA No. 20-4852 ("Aurobindo's ANDA"), seeking approval from the FDA to engage in the commercial manufacture, use and/or sale of generic "trazodone hydrochloride oral tablet 50, 100, 150, and 300 mg" ("Aurobindo's ANDA Product") prior to the expiration of the '893 patent.

4. Plaintiff received Aurobindo's Notice Letter on October 15, 2019.

5. Upon information and belief, Aurobindo's ANDA Product is a drug product that is a generic version of DESYREL®, containing the same or equivalent ingredients in the same or equivalent amounts, which Aurobindo claims is bioequivalent to DESYREL®.

6. Upon information and belief, Aurobindo submitted its ANDA to the FDA containing a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) asserting that the '893 patent is invalid, unenforceable, and/or will not be infringed by the manufacture, use, offer for sale, sale, and/or importation of Aurobindo's ANDA Product.

PARTIES

7. Plaintiff Aziende Chimiche Riunite Angelini Francesco A.C.R.A.F. S.p.A. ("Angelini") is a company organized under the laws of Italy with its principal place of business at Viale Amelia 70, Rome 00181 Italy. Angelini is the assignee of the '893 patent.

8. Upon information and belief, defendant Aurobindo is a corporation organized and existing under the laws of the State of Delaware with its principal place of business at 279 Princeton-Hightstown Road, East Windsor, New Jersey 08520-1401. Upon information and belief, Aurobindo is in the business of, among other things, manufacturing and selling generic versions of branded pharmaceutical products for the U.S. market.

JURISDICTION

9. Jurisdiction is proper in this district pursuant to at least 28 U.S.C. §§ 1331, 1338(a), 2201 and 2202.

10. This Court has personal jurisdiction over Aurobindo. Aurobindo is subject to personal jurisdiction in Delaware because, among other things, it has purposely availed itself of the benefits and protections of Delaware's laws such that it should reasonably anticipate being haled into court here. Aurobindo is a corporation organized and existing under the laws of the State of Delaware, is qualified to do business in Delaware, and has appointed a registered agent for service of process in Delaware at Corporation Service Company, 251 Little Falls Drive, Wilmington, Delaware 19808. It therefore has consented to general jurisdiction in Delaware. In addition, upon information and belief, Aurobindo develops, manufactures, imports, markets, offers to sell, and/or sells generic drugs throughout the United States, including in the State of Delaware and therefore transacts business within the State of Delaware related to Plaintiff's claims, and/or has engaged in systematic and continuous business contacts within the State of Delaware.

11. Upon information and belief, Aurobindo intends that upon approval of Aurobindo's ANDA, Aurobindo will manufacture Aurobindo's ANDA Product and will directly or indirectly market, sell, and distribute Aurobindo's ANDA Product throughout the United States, including in Delaware.

12. Aurobindo has previously used the process contemplated by the Hatch-Waxman Act to challenge branded pharmaceutical companies' patents by filing a certification of the type described in Section 505(j)(2)(A)(vii)(IV) of the Food, Drug, and Cosmetic Act ("FDCA") 21

U.S.C. § 355(j)(2)(A)(vii)(IV), serving a notice letter on those companies, and engaging in patent litigation arising from the process contemplated by the Hatch-Waxman Act.

13. Upon information and belief, Aurobindo, with knowledge of the Hatch- Waxman Act process, directed Aurobindo's Notice Letter to, *inter alia*, Plaintiff, and alleged in Aurobindo's Notice Letter that the '893 patent is invalid and/or will not be infringed by the commercial manufacture, use or sale of the Aurobindo's ANDA Product. Upon information and belief, Aurobindo knowingly and deliberately challenged the '893 patent knowing that when it did so that it was triggering a forty-five day period for Plaintiff to bring an action for patent infringement under the Hatch-Waxman Act.

14. Aurobindo has been a litigant in connection with other infringement actions under the Hatch-Waxman Act, and reasonably should have anticipated that by sending Aurobindo's Notice Letter to Plaintiff, that it would be sued in Delaware for patent infringement.

15. This Court, therefore, also has personal jurisdiction over Aurobindo because Aurobindo regularly engages in patent litigation concerning FDA-approved branded drug products in this district, does not contest personal jurisdiction in this district, and has availed itself of the rights and benefits of this Court by asserting claims and/or counterclaims in this Court. *See, e.g., Millennium Pharmaceuticals, Inc. v. Aurobindo Pharma USA Inc. et al.*, No. 1:19-cv-00471- CFC (D. Del. 2019); *Genentech, Inc. et al. v. Aurobindo Pharma USA Inc. et al.*, No. 1:19-cv- 00105-RGA (D. Del. 2019); *Allergan Sales, LLC et al. v. Aurobindo Pharma USA, Inc. et al.*, No. 1:18-cv-001180-GMS (D. Del. 2018); *Kissei Pharmaceutical Co. Ltd. et al. v. Aurobindo Pharma USA Inc. et al.*, No. 1:17-cv-01161-LPS (D. Del. 2017).

16. Upon information and belief, if Aurobindo's ANDA is approved, Aurobindo will directly or indirectly manufacture, market, sell, and/or distribute Aurobindo's ANDA Product

within the United States, including in Delaware, consistent with Aurobindo's practices for the marketing and distribution of other generic pharmaceutical products. Upon information and belief, Aurobindo regularly does business in Delaware, and its practices with other generic pharmaceutical products have involved placing those products into the stream of commerce for distribution throughout the United States, including in Delaware. Upon information and belief, Aurobindo's generic pharmaceutical products are used and/or consumed within and throughout the United States, including in Delaware. Upon information and belief, Aurobindo's ANDA Product will be prescribed by physicians practicing in Delaware, dispensed by pharmacies located within Delaware, and used by patients in Delaware. Each of these activities would have a substantial effect within Delaware and would constitute infringement of the '893 patent in the event that Aurobindo's ANDA is approved before the patent expires.

17. Upon information and belief, Aurobindo derives substantial revenue from pharmaceutical products that are used and/or consumed within Delaware, and which are manufactured by Aurobindo and/or for which Aurobindo is the named applicant on approved ANDAs. Upon information and belief, various products for which Aurobindo is the named applicant on approved ANDAs are available at retail pharmacies in Delaware.

18. For the foregoing reasons, this Court has personal jurisdiction over Aurobindo.

VENUE

19. Venue is proper in this district for Aurobindo pursuant to 28 U.S.C. §§ 1391 and 1400(b) because, *inter alia*, as a corporation organized and existing under the laws of the State of Delaware, Aurobindo is deemed to reside in this judicial district, and is subject to personal jurisdiction in this judicial district.

THE '893 PATENT

20. The inventors named on the '893 patent are Marcello Marchetti, Tommaso Iacoangeli, Giovanni Battista Ciottoli and Giuseppe Biondi (collectively, "the Named Inventors").

21. The '893 patent, entitled "Trazodone and Trazodone Hydrochloride in Purified Form," was duly and legally issued on March 12, 2012, to Angelini as assignee of the Named Inventors. A copy of the '893 patent is attached as **EXHIBIT A**.

22. The '893 patent claims, *inter alia*, trazodone or trazodone hydrochloride comprising less than 15 parts per million of alkylating substances, a pharmaceutical composition of trazodone hydrochloride, and a process of production of trazodone or trazodone hydrochloride.

23. Angelini is assignee of the '893 patent, and has the right to enforce the '893 patent.

24. DESYREL®, and methods of producing DESYREL®, are covered by one or more claims of the '893 patent.

25. The '893 patent has been listed in connection with DESYREL® in the FDA's publication, *Approved Drug Products with Therapeutic Equivalence Evaluations*, which is referred to as the "Orange Book."

26. Plaintiff will be substantially and irreparably damaged by infringement of the '893 patent because Angelini is the exclusive supplier of the active pharmaceutical ingredient in DESYREL®.

COUNT I – AUROBINDO'S INFRINGEMENT OF THE '893 PATENT

27. Plaintiff incorporates each of the preceding paragraphs 1–26 as if fully set forth herein.

I. Direct Infringement

28. In Aurobindo's Notice Letter, Aurobindo notified Plaintiff that it had submitted Aurobindo's ANDA to the FDA. The purpose of the submission of the ANDA was to obtain approval to engage in the commercial manufacture, use, offer for sale, sale and/or importation of Aurobindo's ANDA Product in the United States prior to the expiration of the patent-in-suit.

29. In its Notice Letter, Aurobindo also notified Plaintiff that, as part of its ANDA, Aurobindo had filed certifications of the type described in Section 505(j)(2)(A)(vii)(IV) of the FDCA, 21 U.S.C. § 355 (j)(2)(A)(vii)(IV), with respect to the '893 patent.

30. Aurobindo's ANDA is an application for a drug claimed in one or more claims of the '893 patent, including at least claim 1.

31. Aurobindo has knowledge of the '893 patent.

32. Aurobindo's submission of its ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of its ANDA Product in the United States before the expiration of the '893 patent was an act of infringement of that patent under 35 U.S.C. § 271(e)(2)(A).

33. Upon information and belief, Aurobindo will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of its ANDA Product in the United States immediately and imminently upon approval of its ANDA and expiration of any other Orange Book-listed patent or relevant exclusivity for the DESYREL® product.

34. The manufacture, use, sale, offer for sale, and/or importation of Aurobindo's ANDA Product in the United States would infringe one or more claims of the '893 patent, including at least claim 1.

35. Upon information and belief, the manufacture, use, sale, offer for sale, and/or importation of Aurobindo's ANDA Product in the United States in accordance with, and as directed by Aurobindo's proposed product labeling would infringe one or more claims of the '893 patent, including at least claim 1.

II. Indirect Infringement: Contributory Infringement

36. Upon information and belief, for at least the following reasons, Aurobindo plans and intends to, and will, actively indirectly infringe the '893 patent when its ANDA is approved, and plans and intends to, and will, do so immediately and imminently upon approval.

37. Upon information and belief, Aurobindo knows that Aurobindo's ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '893 patent, that Aurobindo's ANDA Product is not a staple article or commodity of commerce, and that Aurobindo's ANDA Product and its proposed labeling are not suitable for substantial noninfringing use. Upon information and belief, Aurobindo plans and intends to, and will, contribute to infringement of the '893 patent immediately and imminently upon approval of Aurobindo's ANDA and expiration of any other Orange Book-listed patent or relevant exclusivity for the DESYREL® product.

38. Notwithstanding Aurobindo's knowledge of the claims of the '893 patent, Aurobindo has continued to assert its intent to manufacture, offer for sale, sell, distribute, and/or import Aurobindo's ANDA Product with its product labeling upon FDA approval of Aurobindo's ANDA and prior to the expiration of the '893 patent.

III. Indirect Infringement: Inducement of Infringement

39. Upon information and belief, Aurobindo knows that Aurobindo's ANDA Product will induce the direct infringement of the '893 patent by a number of direct infringers, including,

but not limited to Aurobindo's customers, distributors, affiliates, employees and manufacturers. Upon information and belief, Aurobindo plans and intends to, and will, induce others to directly infringe the '893 patent immediately and imminently upon approval of Aurobindo's ANDA and expiration of any other Orange Book-listed patent or relevant exclusivity for the DESYREL® product.

40. Notwithstanding Aurobindo's knowledge of the claims of the '893 patent, Aurobindo has continued to assert its intent to manufacture, offer for sale, sell, distribute, and/or import Aurobindo's ANDA Product in the United States with its product labeling upon FDA approval of Aurobindo's ANDA and prior to the expiration of the '893 patent ,with the knowledge that such activities will induce direct infringement of the '893 patent by others.

41. The foregoing actions by Aurobindo, with Aurobindo's knowledge detailed above, constitute and/or will constitute infringement of the '893 patent; active inducement of infringement of the '893 patent; and/or contribution to the infringement by others of the '893 patent.

42. Upon information and belief, Aurobindo has acted with full knowledge of the '893 patent and without a reasonable basis for believing that it would not be liable for infringement of the '893 patent; active inducement of infringement of the '893 patent; and/or contribution to the infringement by others of the '893 patent.

43. Unless Aurobindo is enjoined from infringing the '893 patent, actively inducing infringement of the '893 patent, and contributing to the infringement by others of the '893 patent, Plaintiff will suffer irreparable injury because Plaintiff is the exclusive supplier of the active pharmaceutical ingredient covered by the '893 patent. Plaintiff has no adequate remedy at law.

COUNT II – DECLARATORY JUDGMENT OF INFRINGEMENT BY AUROBINDO OF THE '893 PATENT

44. Plaintiff incorporates paragraphs 1–43 as if fully set forth herein.

45. The Court may declare the rights and legal relations of the parties pursuant to 28 U.S.C. §§ 2201 and 2202 because there is a case of actual controversy between Plaintiff on the one hand and Aurobindo on the other regarding Aurobindo's infringement, active inducement of infringement, and contribution to the infringement by others of the '893 patent.

46. The Court should declare that the commercial manufacture, use, sale, offer for sale and/or importation of Aurobindo's ANDA Product, or any other drug product which is covered by, or use of which is covered by one or more claims of the '893 patent, will infringe, induce the infringement of, or contribute to the infringement by others of, that patent.

47. Plaintiff will be irreparably harmed by the sale of Aurobindo's ANDA Product because Plaintiff is the exclusive supplier to third parties that sell or plan to sell pharmaceutical drugs containing of the active pharmaceutical ingredient covered by the '893 patent.

WHEREFORE, Plaintiff requests the following relief:

(a) A judgment that each claim of the '893 patent has been infringed under 35 U.S.C. § 271(e)(2) by Aurobindo's submission to the FDA of Aurobindo's ANDA;

(b) A judgment ordering that the effective date of any FDA approval of commercial manufacture, use, or sale of Aurobindo's ANDA Product, or any other drug product that infringes or the use of which infringes one or more claims of the '893 patent, be not earlier than the latest of the expiration dates of the '893 patent, inclusive of any extension(s) and additional period(s) of exclusivity;

(c) A preliminary and permanent injunction enjoining Aurobindo, and all persons acting in concert with Aurobindo, from the commercial manufacture, use, sale, offer for sale, or

importation into the United States of Aurobindo's ANDA Product, or any other drug product covered by or whose use is covered by one or more of the claims of the '893 patent, prior to the expiration of said patent, inclusive of any extension(s) and additional period(s) of exclusivity;

(d) A judgment declaring that the commercial manufacture, use, sale, offer for sale or importation of Aurobindo's ANDA Product, or any other drug product which is covered by or whose use is covered by one or more of the claims of the '893 patent, prior to its expiration, will infringe, induce the infringement of, and contribute to the infringement by others of, the '893 patent;

(e) A declaration that this is an exceptional case and an award of attorneys' fees pursuant to 35 U.S.C. § 285;

(f) Costs and expenses in this action; and

(g) Such further and other relief as this Court may deem just and proper.

Dated: November 25, 2019

YOUNG CONAWAY STARGATT & TAYLOR LLP

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